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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/887,762	06/22/2001	David L. Thompson	P-9148.00	8719

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MEDTRONIC, INC.
710 MEDTRONIC PARK
MINNEAPOLIS, MN 55432-9924

EXAMINER	
RINES, ROBERT D	

ART UNIT	PAPER NUMBER
3626	

DATE MAILED: 08/31/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/887,762	THOMPSON, DAVID L.	
	Examiner	Art Unit	
	Robert D. Rines	3626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 April 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-14* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-14* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Notice to Applicant

[1] This communication is in response to the amendment filed 18 April 2006. Claims 1, 3-6, 8, and 10 have been amended. Claims 1-14 are pending.

Claim Rejections - 35 USC § 112

[2] Previous rejections of claims 3, 6, 8, 10 and 12 under 35 U.S.C. 112, second paragraph, set forth in the Office Action mailed 20 January 2006 are hereby withdrawn.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

[3] Claims 1-5 and 7-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Levine et al. (United States Patent #6,327,501) in view of Karp et al. (United States Patent #6,591,242) and further in view of DeLorme et al. (United States Patent #5,948,040).

As per (currently amended) claim 1, Levine et al. discloses a portable device for use by a visiting nurse to access patient data comprising: means for establishing a wireless data communication with the one or more IMDs in the patient (Levine et al.; Abstract and col. 3, lines 3-31, col. 5, lines 45-51 and, col. 6, lines 12-26); means for downloading patient data from the one or more IMDs (Levine et al.; Abstract and col. 3, lines 3-31 and col. 6, lines 12-26); and a touch screen coupled to said means for establishing and said means for downloading providing a user input to activate the same (Levine et al.; col. 5, lines 45-51).

*NOTE: Although the Levine et al. invention is primarily directed to modifications of a portable IMD external programmer that impart additional functionality on the portable external programmer (i.e., a safety alert method/system), Levine, by incorporated reference (Levine et al.; col. 5, lines 45-51), discloses a pen-based tablet computer/external programmer (i.e., data extraction and entry functions are initiated and controlled by touching a screen with a pen)).

Levine et al. fails to specifically disclose means for positively identifying the visiting nurse and computer implemented software for planning and organizing a daily schedule of patient visits for the visiting nurse among a plurality of patients.

However, Karp et al. teaches means for positively identifying the visiting nurse (Karp et al.; Abstract, col. 7, lines 4-19 and col. 9, lines 47-55).

The device disclosed by Karp et al. is directed to tracking the location of and services performed by a nurse or healthcare professional visiting patients (Karp et al.; col. 7, lines 4-19 and col. 9, lines 47-55). Karp et al. further teaches software modules to enable the functions of communication, client (e.g., nurse) identification, location identification, arrival and departure information, service code recording, and report generation (Karp et al.; col. 5, lines 39-50 and col. 9, lines 47-55). While the above noted features of Karp et al. indicate to the Examiner that planning or scheduling of tasks/visits features are likely included in the Karp et al. device, Karp et al. fails to expressly disclose software enabling a nurse to plan a daily schedule for visiting patients.

However, as is evidenced by DeLorme et al. portable devices that couple navigational information (GPS derived or other) with scheduling, route planning, and mapping features provided by executable software are well-known (DeLorme et al.; Abstract, col. 4, lines 43-61 and col. 7, lines 22-51).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have combined the teachings of Levine et al. with those of Karp et al. and DeLorme et al. Such combination would have resulted in a portable and functionally modifiable device that

provided for the collection of patient data including the retrieval of stored information/data from an implantable medical device associated with each patient (Levine et al.; Abstract and col. 3, lines 3-31 and col. 6, lines 12-26). Additionally, such a device would have included GPS and biometric identification sensors to track and assist the nurse in visiting the required locations and to positively identify the nurse (Karp et al.; Abstract, col. 7, lines 4-19 and col. 9, lines 47-55). Further, such a device would have employed well-known trip planning/scheduling features that utilize GPS-derived position information in conjunction with incorporated software modules designed to allow a user of the device to custom-define and examine a travel route including establishing waypoints (i.e., visit stops) (DeLorme et al.; col. 6, lines 56-67). The motivation to combine the teachings would have been to expand the user assistance features of a known and functionally modifiable portable device equipped with a telemetry circuit capable of exchanging information with an implantable medical device, to incorporate advances in biometric security features (Karp et al.; Abstract, col. 7, lines 4-19 and col. 9, lines 47-55) and GPS-based navigational assistance features designed to assist a user of the device with planning travel routes (DeLorme et al.; col. 6, lines 56-67). Additional motivation would have been to provide a device that enables the tracking of healthcare professionals as they visit various patients and to record the services rendered (i.e., acquisition of patient data) at each location (Karp et al.; Abstract and col. 1, lines 16-24).

As per claim 2, Levine et al. discloses wireless data communication means includes a telemetry system (Levine; Abstract and col. 3, lines 13-16).

Regarding claim 2, the obviousness and motivation to combine as discussed with respect to claim 1 above are applicable to claim 2 and are herein incorporated by reference.

As per (currently amended) claim 3, Karp et al. teaches means for identifying is selected from the groups consisting of a video cam, a voice recognition system, a digital signature recognition system, a biological/physiological sensor (Karp et al.; col. 7, lines 4-19).

Regarding claim 3, the obviousness and motivation to combine as discussed with respect to claim 1 above are applicable to claim 3 and are herein incorporated by reference.

As per (currently amended) claim 4, Karp et al. teaches a video cam is implemented to capture images of the nurse (Karp et al.; col. 3, lines 2-29 and col. 4, lines 1-17).

NOTE: Karp et al. teaches the use of an identification device to acquire and subsequently transmit an image of a fingerprint or iris for identification purposes (Karp et al.; Abstract and col. 4, lines 8-17). Examiner interprets the teachings of Karp et al., in which a device is used to acquire an image of the user's fingerprint or iris as encompassing of Applicant's use of a "video cam" to acquire images of the visiting nurse.

As per (currently amended) claim 5, Karp et al. teaches wherein said images are transferred to a remote location (Karp et al.; Abstract and col. 4, lines 8-17).

Regarding claims 4 and 5, the obviousness and motivation to combine as discussed with regard to claim 1 above are applicable to claims 4 and 5 and are herein incorporated by reference.

As per claim 7, while Levine discloses a pen-based tablet computer, capable of receiving data transmitted from a medical device implanted in a patient via wireless connection or telemetry (Levine; col. 5, lines 19-21 and lines 45-51 *see analysis claim 1), Levine does not teach inclusion of a GPS in the tablet computer to plot a most efficient sequence of visits to patients.

However, Karp et al. teaches including a GPS system imbedded to enable the nurse to adhere to a schedule of patient visits (Karp et al.; col. 3, lines 15-29 and col. 10, lines 8-15). Karp et al. does not specifically state that the nurse utilizes the GPS equipped device to plot a most efficient sequence of patient visits.

However, as is evidenced by DeLorme et al. portable devices that couple navigational information (GPS derived or other) with scheduling, route planning, and mapping features provided by executable software are well-known (i.e., features that enable a visiting nurse to plot a most efficient sequence of visits to patients scheduled at a given time) (DeLorme et al.; Abstract, col. 4, lines 43-61 and col. 7, lines 22-51).

Regarding claim 7, the obviousness and motivation to combine as discussed with regard to claim 1 above are applicable to claim 7 and are herein incorporated by reference.

As per (currently amended) claim 8, Karp et al. teaches means for identifying includes means for comparing physical data selected from a group consisting of fingerprint, facial, voice and iris data against data stored in the portable extender (Karp et al.; col. 7, lines 4-19).

Regarding claim 8, the obviousness and motivation to combine as discussed with regard to claim 1 above are applicable to claim 8 and are herein incorporated by reference.

As per claim 9, Karp et al. teaches wherein data is transferred via a wireless communication link including one of a cellular and satellite system (Karp et al.; col. 3, lines 40-59).

Regarding claim 9, the obviousness and motivation to combine as discussed with regard to claim 1 above are applicable to claim 9 and are herein incorporated by reference.

As per (currently amended) claim 10, Levine et al. discloses a portable extender adapted for use by a visiting nurse to manage home-based care among a plurality of patients, each patient having an IMD, comprising: means for downloading data from the IMD (Levine et al.; Abstract and col. 3, lines 3-31, col. 5, lines 45-51, col. 6, lines 12-26 *see analysis claim 1) and means for storing, compiling and managing said IMD data (Levine et al.; col. 4, lines 33-67, col. 6, lines 64-67, and col. 7, lines 9-35). Levine et al. fails to teach downloading patient location, entering non-IMD medical data, transferring medical patient and medical data to a remote location, and software for planning a daily schedule of patient visits.

However, Karp et al. teaches means for downloading patient data including patient location (Karp et al.; Abstract and col. 5, lines 65-67, and col. 6, lines 1-12); means for entering non-IMD medical data (Karp et al.; col. 5, line 44, col. 6, lines 42-56 and col. 8, lines 33-50); and means for transferring the patient and medical data to a remote location (Karp et al.; col. 13, lines 3-11).

The device disclosed by Karp et al. is directed to tracking the location of and services performed by a nurse or healthcare professional visiting patients (Karp et al.; col. 7, lines 4-19 and col. 9, lines 47-55). Karp et al. further teaches software modules to enable the functions of communication, client (e.g., nurse) identification, location identification, arrival and departure information, service code recording, and report generation (Karp et al.; col. 5, lines 39-50 and col. 9, lines 47-55). While the above noted features of Karp et al. indicate to the Examiner that planning or scheduling of tasks/visits features are likely included in the Karp et al. device, Karp et al. fails to expressly disclose computer implemented software for planning and organizing a daily schedule of patient visits for the visiting nurse among a plurality of patients.

However, as is evidenced by DeLorme et al. portable devices that couple navigational information (GPS derived or other) with scheduling, route planning, and mapping features provided by executable software are well-known (DeLorme et al.; Abstract, col. 4, lines 43-61 and col. 7, lines 22-51).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have combined the teachings of Levine et al. with those of Karp et al. and DeLorme et al.

Such combination would have resulted in a portable and functionally modifiable device that provided for the collection of patient data including the retrieval of stored information/data from an implantable medical device associated with each patient (Levine et al.; Abstract and col. 3, lines 3-31 and col. 6, lines 12-26). Additionally, such a device would have included GPS and biometric identification sensors to track and assist the nurse in visiting the required locations and to positively identify the nurse (Karp et al.; Abstract, col. 7, lines 4-19 and col. 9, lines 47-55). Further, such a device would have employed well-known trip planning/scheduling features that utilize GPS-derived position information in conjunction with incorporated software modules designed to allow a user of the device to custom-define and examine a travel route including establishing waypoints (i.e., visit stops) (DeLorme et al.; col. 6, lines 56-67). The motivation to combine the teachings would have been to expand the user assistance features of a known and functionally modifiable portable device equipped with a telemetry circuit capable of exchanging information with an implantable medical device, to incorporate advances in biometric security features (Karp et al.; Abstract, col. 7, lines 4-19 and col. 9, lines 47-55) and GPS-based navigational assistance features designed to assist a user of the device with planning travel routes (DeLorme et al.; col. 6, lines 56-67). Additional motivation would have been to provide a device that enables the tracking of healthcare professionals as they visit various patients and to record the services rendered (i.e., acquisition of patient data) at each location (Karp et al.; Abstract and col. 1, lines 16-24).

As per claim 11, Karp et al. teaches means for downloading a daily schedule includes one of IvDA, RF cellular and satellite link between the portable extender and a remote clinic/physician station (Karp et al.; col. 3, lines 50-59 and col. 4, lines 38-50).

NOTE: Karp et al. employs both wired or wireless connections between the GPS enabled portable computer and the database (Karp et al.; col. 3, lines 50-59).

As per claim 12, Karp et al. teaches means for downloading patient location includes an imbedded GPS system (Karp et al.; col. 10, lines 8-15). Karp et al. fails to specifically teach including software to calculate the most efficient sequence of patient visits scheduled for the nurse.

However, as is evidenced by DeLorme et al. portable devices that couple navigational information (GPS derived or other) with scheduling, route planning, and mapping features provided by executable software are well-known (DeLorme et al.; Abstract, col. 4, lines 43-61 and col. 7, lines 22-51).

Regarding claims 11 and 12, the obviousness and motivation to combine as discussed with regard to claim 10 above are applicable to claims 11 and 12 and are herein incorporated by reference.

[4] Claims 6 and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Levine et al., Karp et al., and DeLorme et al., as applied to claims 1 and 10 above, and further in view of Evans (United States Patent #5,924,074).

As per (currently amended) claim 6, as noted above with respect to claim 1, Levine et al. teaches the accessed medical data includes data retrieved from IMD device (Levine et al.; Abstract and col. 3, lines 3-31 and col. 6, lines 12-26) but fails to teach transfer of images for identification purposes.

However, Karp et al. teaches transferring images to a remote location to identify the nurse (Karp et al.; Abstract and col. 11, lines 65-67 and col. 12, lines 1-16). While Karp et al. teaches terminating the connection if appropriate biometric identification of the user is not made (Karp et al.; col. 11, lines 65-67 and col. 12, lines 1-16), Karp et al. fails to teach releasing privileged data to the user upon positive identification of the user.

However, as is evidenced by Evans, the use of security measures to identify a requesting individual prior to releasing and allowing access to confidential or privileged medical information is well known in the electronic medical records and remote patient care arts (Evans; col. 15, lines 9-32).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have combined the teachings of Levine et al., Karp et al., and DeLorme et al., as applied to

claim 10 above, with those of Evans. Such combination would have resulted in a patient data acquisition and entry device equipped to acquire and transmit images associated with a unique physiological characteristic of the visiting nurse for the purpose of identifying the nurse or healthcare professional prior to enabling electronic transactions to occur between the nurse and the database (Karp et al.; col. 11, lines 65-67 and col. 12, lines 1-18). In addition to providing biometric security measures to insure only identified individuals enter information into a database, such a system would have utilized the same security features to ensure the only positively identified and authorized individuals access confidential patient data (Evans; col. 15, lines 9-32). The motivation to combine the teachings would have been to provide superior protection of patient data (Evans; col. 15, lines 31-32).

As per claim 13, while Karp et al. teaches means for entering non-IMD patient data, Karp et al. is primarily directed to tracking visits and treatments/tasks performed by a visiting nurse. Karp et al. fails to expressly disclose that data gathered includes physiological data or that physiological data is updated in a database during the nurse's visit.

However, Evans teaches means for entering non-IMD medical data includes a database where additional physiological data about the patient is entered and updated during the nurse's visit (Evans; col. 2, lines 45-57).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have combined the teachings of Levine et al., Karp et al., and DeLorme et al., as applied to

claim 10 above, with those of Evans. The motivation to combine the teachings would have been enable the transfer and maintenance of data relevant to the treatment of a patient to remote locations (Evans; col. 2, lines 10-18).

[5] Claim 14 is rejected under 35 U.S.C. 103(a) as being unpatentable over Levine et al., Karp et al., and DeLorme et al., as applied to claim 10 above, and further in view of Evans and Miller (United States Patent #5,235,702).

As per claim 14, while Karp et al. teaches auditing and billing features associated with home care medical visits (Karp et al.; col. 4, lines 39-59), Karp et al. fails to specifically teach accessing patient medication information, a pharmacist contact database, or an expert consultation database. Additionally, Medicare form generation is not specifically included in the billing features of Karp et al.

However, Evans teaches software to access patient medication information (Evans; col. 2, lines 35-44), pharmacist contact data bases (Evans; col. 2, lines 47-64 and col. 11, lines 1-5), and physician expert contact/consulting database (Evans; col. 2, lines 47-64). Although Evans teaches database including information related to payment and reimbursement (Evans; col. 5, lines 37-40), Evans fails to specifically teach Medicare reimbursement functions or Medicare form generation.

However, Miller teaches Medicare form generation (Miller; col. 7, lines 62-68).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have combined the teachings of Levine et al., Karp et al., and Delorme et al., as applied to claim 10 above, with those of Evans and with those of Miller. Such combination would have expanded upon the specific data and information available to the visiting nurse to include the capability to access reference databases for consultation regarding allergies, medication interactions, and practice guidelines (Evans; Abstract). The motivation to combine the teachings of Levine et al., Karp et al., and DeLorme et al., with those of Evans would have been to enhance analysis of patient data by providing access to reference databases for diagnosis, procedures and medication (Evans; col. 2, lines 60-64). Further motivation to combine the additional teachings of Miller would have been include in such a system, the feature of providing a computer readable document of known format (Miller; Abstract) that is relevant to most commonly required medical billing formats (Miller; col. 1, lines 18-30).

Response to Arguments

Applicant's arguments filed 18 April 2006 have been fully considered by the Examiner and are considered moot in view of newly added grounds of rejection.

In response, all of the limitations which Applicant disputes as missing in the applied references, including the features newly added in the 18 April 2006 amendment have been fully addressed by the Examiner as either being fully disclosed or obvious in view of the collective teachings of

newly added references Karp et al. and DeLorme et al., and previously applied references Levine et al., Evans, and Miller, based on the logic and sound scientific reasoning of one ordinarily skilled in the art at the time of the invention, as detailed in the remarks and explanations given in the preceding sections of the present Office Action and in the prior Office Action (mailed 20 January 2006), and incorporated herein.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert D. Rines whose telephone number is 571-272-5585. The examiner can normally be reached on 8:30am - 5:00pm Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Thomas can be reached on 571-272-6776. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

RDR

JOSEPH THOMAS
SUPERVISORY PATENT EXAMINER